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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/402,680	01/10/2000	HANS-PETER SCHWARZ	BHV-313.01	6277

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EXAMINER

FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 09/23/2002

29

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/402,680

Applicant(s)

Schwarz et al.

Examiner

Michele Flood

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Jul 11, 2002
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 43-49, 51-62, 73, and 75-81 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 43-49, 51-62, 73, and 75-81 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other: \_\_\_\_\_

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### **DETAILED ACTION**

Acknowledgment is made of the receipt and entry of the amendment filed on July 11, 2002. Acknowledgment is made of Applicant's cancellation of Claims 50, 63-72 and 74, and newly added Claims 76-81.

Claims 43-49, 51-62, 73, and 75-81 are under examination.

The rejection made under 35 U.S.C. 112, first paragraph, has been overcome by Applicant's amendment.

The rejection made under 35 U.S.C. 112, second paragraph, has been overcome by Applicant's amendment.

The objection made under 37 CFR 1.75(c) has been overcome by Applicant's cancellation of Claim 50, and the amendments made to Claims 73 and 75.

### ***Response to Arguments***

Applicant's arguments have been fully considered but they are not persuasive.

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***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 43-49, 51-52, 55-62, 73 and 75-81 as amended remain/are rejected under 35 U.S.C. 102(b) as being anticipated by Chandra et al. (A).

Applicant claims a method of inactivating microorganisms and pyrogens present in a biological material comprising: adsorbing a biological material to a solid carrier, wherein the biological material comprises proteins; and incubating said material in the presence of an alkyl phosphate-free detergent solution, wherein said detergent solution contains at least one eluotropic salt in a total concentration of at least 200mM, wherein during incubation said proteins are desorbed into the detergent solution to yield a suspension and said microorganisms and pyrogens are inactivated, and a biological preparation thereof.

Applicant argues that the teachings of Chandra fail to anticipate the claimed subject because Applicant relies on the reading of the abstract as the basis for the traversal of the rejection. However, Applicant's arguments are not found persuasive because Chandra teaches a method for inactivating microorganisms and pyrogens present in biological materials comprising the steps of adsorbing the biological material onto a solid phase; treating the adsorbed product

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with a virus or pyrogen inactivating agent; separating the solid phase and removing the residual inactivating agent; and recovering the product. The method Chandra' method can be applied to various biomedical materials, e.g., blood protein fractions and blood factors, which are adsorbed onto a solid carrier, such as an ion exchanger and resins used for affinity chromatography, etc. See Column, lines 22-68 to Column 3, lines 1-27. In Column 2, lines 28-68 to Column 4, lines 1-60, Chandra teaches non-ionic detergents, such as polyoxyethylene ether detergents, as inactivating agents which are present in amounts of from 0.1 to 50%, 0.5%-20%, or 1-10% based on the volume of the product. The incubation time taught by Chandra is generally in the range of 1 to 10 hours. In Column 9, lines 6-24, under "EXAMPLE 5", Chandra expressly teaches a method of depyrogenizing a biological material to obtain a purified Antithrombin III preparation. Chandra expressly teaches the claimed subject matter in Column 9, lines 26-54, wherein Chandra teaches a method of inactivating microorganisms and pyrogens in a proteinaceous biological material comprising adsorbing monoclonal antibody against Factor VIII:R to sepharose resin, and packed in a column. "A suspension of cryoprecipitate is spike with VSV, as a controlled experiment . . . It is then passed through the column where Factor VIII molecules (which consist of subunits of Factor VIII:C Antigen and Factor VIII:R Antigen portion of the molecule. The resin is then treated with 2% Tween 80 solution in a wash buffer consisting of 100mM lysine, 20 mM histidine, 0.15M sodium chloride, at pH 7.0, to inactivate virus." Chandra further teaches removing residual Tween 80 by washing the column using the above mentioned wash buffer, desorbing Factor VIII:C by an elution buffer consisting of 0.25M calcium chloride in the wash

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buffer, and desorbing Factor VIII:R antigen with sodium thiocyanate in the above mentioned wash buffer. Finally, Chandra teaches concentrating and purifying by dialysis against physiological saline to provide that are practically free of virus. See entire document and claims.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 43-49, 51-62, 73 and 75-81 rejected under 35 U.S.C. 103(a) as being unpatentable over Chandra et al. (A) in view of Hrinda et al. (N) and Eibl et al. (B).

Applicant's claimed invention was set forth above. Applicant further claims a method according to claim 43 wherein said elutropic salt is a chaotropic agent; and wherein said chaotropic agent is selected from the group consisting of urea, rhodanides, and guanidinium.

The teachings of Chandra were set forth above. Chandra teaches the claimed invention except for a chaotropic agent. However, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the teachings of Chandra by adding a chaotropic agent because Hrinda and Eibl teach chaotropic agents that are effective in inactivating microorganisms and pyrogens present in biological materials. Firstly, Hrinda teaches methods of inactivating viruses in a blood product, which comprises labile proteins and

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viruses, comprising contacting the blood product with chaotropic agents, e.g., sodium thiocyanate and EDTA. On page 15, lines 19-23, Hrinda further teaches that sodium thiocyanate is used in an amount of 0.5M to 2M. The method taught by Hrinda comprises the steps of chromatographing a blood product to a carrier; eluting the chromatographed blood product; incubating the biological material to inactivate viruses; and, separating the chemical disinfectant from the active blood product by dialysis (optional step); and, physically removing the inactivated and active viruses from the blood product. See page 14, lines 8 to page 15, lines 1-11. Secondly, Eibl teaches a method of inactivating infectious agents present in a biological material containing proteins comprising contacting the biological material with chaotropic agent such as thiocyanate, urea or guanidinium salt. See Column 4, lines 45 to Column 5, lines 1-9. At the time the invention was made, one of ordinary skill in the art would have been motivated and one would have had a reasonable expectation of success to add the chaotropic agents taught by Hrinda and Eibl to the method taught by Chandra because Hrinda teaches that his method provides a blood product which comprises a labile blood protein free of viruses without incurring protein denaturation and Eibl teaches that treating biological materials in the presence of the disclosed chaotropic agents inactivates infectious agents while effecting a preferred biological activity of the product produced thereof.

Accordingly, the claimed invention was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

**No claims are allowed.**

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***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Michael Wityshyn whose telephone number is (703) 308-4743.

MCF

September 18, 2002



**CHRISTOPHER R. TATE  
PRIMARY EXAMINER**